UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION))) MDL NO. 1456
) CIVIL ACTION: 01-CV-12257-PBS
THIS DOCUMENT RELATES TO ALL ACTIONS)) Judge Patti B. Saris)

MEMORANDUM IN SUPPORT OF GLAXOSMITHKLINE'S MOTION TO DISMISS

Defendant SmithKline Beecham Corporation, d/b/a GlaxoSmithKline ("GSK"), respectfully submits this memorandum in support of its motion to dismiss the Master Consolidated Class Action Complaint ("Master Complaint" or "Cplt."). The claims against GSK should be dismissed not only for the reasons stated in the Consolidated Memorandum, but also for two reasons unique to GSK -- (1) only one of the plaintiffs has standing to sue GSK, as none of the other plaintiffs alleges a payment for any GSK drug; and (2) even as to that plaintiff, the only remotely particularized allegations of fraud relate to just two GSK drugs, Kytril and Zofran. Thus, if the Court does not dismiss the claims against GSK for the reasons set forth in the Consolidated Memorandum, it should still enter an order limiting the claims against GSK to just one plaintiff asserting overpayments for two drugs.¹

I. WITH ONE EXCEPTION, ALL PLAINTIFFS LACK STANDING TO SUE GSK.

Of the thirty-four plaintiffs in this case, only <u>one</u>, the Teamsters Health & Welfare Fund of Philadelphia ("THWF"), is alleged to have purchased any prescription drug presently or

¹ GSK also joins in the motion, filed today, to strike paragraphs 155-56 of the Master Complaint.



formerly manufactured by GSK. THWF alleges in paragraph 24 that it "paid charges" for "GSK's Navelbine, Kytril, and Zofran." Cplt. ¶ 24. Several of the individual patient plaintiffs and the other employee benefit plan plaintiffs identify payments for drugs made by <u>other</u> companies, yet THWF is the only one who alleges payment for a GSK drug. Thus, only THWF has standing to sue GSK (and then only for its alleged payments for Kytril and Zofran, for the reasons expressed below).

Standing is a "threshold question in every federal case, determining the power of the court to entertain the suit." *United States v. AVX Corp.*, 962 F.2d 108, 113 (1st Cir. 1992) (quoting Warth v. Seldin, 422 U.S. 490, 498 (1975)). In order to have standing under Article III, each plaintiff "must allege personal injury fairly traceable to the defendant's alleged unlawful conduct and likely to be redressed by the requested relief." *Allen v. Wright*, 468 U.S. 737, 751 (1984) (citations omitted). At the pleading stage, the plaintiffs bear the burden to demonstrate standing by asserting factual allegations of injury. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992); see also Guckenberger v. Boston University, 957 F. Supp. 306, 320 (D. Mass. 1997) (Saris, J.) ("[T]he burden of adducing facts necessary to support standing rests squarely with the party seeking to avail itself of federal jurisdiction") (quoting AVX, Inc., 962 F.2d at 114).

Obviously, if a plaintiff fails to allege that it purchased a GSK drug, it cannot demonstrate that its injuries are "fairly traceable" to GSK's conduct. *See Paracelsus Corp.*Securities Litig., 6 F. Supp. 2d 626, 631 (S.D. Tex. 1998) (dismissing class action securities law claim where named plaintiffs did not allege they had purchased the securities at issue, even though other members of the purported class had purchased them). This is true not only for the individual plaintiffs and three of the four employee benefit plan plaintiffs, which do not allege

payment for any GSK drug, but also for the association plaintiffs that seek to pursue claims on behalf of their members. Each association plaintiff must show that "at least one of [its] members possesses standing to sue in his or her own right." *AVX, Corp.*, 962 F.2d at 116. Yet none of the association plaintiffs alleges that any of its members purchased any GSK drug. *See AVX, Inc.*, 962 F.2d at 116-17 (dismissing appeal for lack of standing where association made only "nebulous" and "generalized" allegations regarding injury to unspecified members); *Pennsylvania Protection and Advocacy, Inc. v. Houston*, 136 F. Supp. 2d 353, 365-66 (E.D. Pa. 2001) (association lacked standing to pursue claims of members because it never alleged "demonstrable, particularized injury" to any member). And even if any association alleged that its members purchased a GSK drug, the associations cannot sue for damages on behalf of those members. *Warth*, 422 U.S. at 515-16.²

II. THE CLAIMS AGAINST GSK RELATING TO DRUGS OTHER THAN KYTRIL OR ZOFRAN MUST BE DISMISSED PURSUANT TO RULE 9(b).

Even if more than one plaintiff had alleged payment for a GSK drug, the claims against GSK still must be limited only to two Medicare-eligible drugs, Kytril and Zofran. Those two products are the only GSK drugs about which plaintiffs make any remotely specific allegations of fraud.

With one very minor exception, the Master Complaint is silent about any GSK drug other than Kytril or Zofran, which are used to relieve the nausea induced by chemotherapy.

The plaintiffs who made no payments for GSK drugs cannot avoid dismissal of their claims against GSK by maintaining these claims on behalf of class members who may have made payments for GSK drugs. See In re Taxable Mun. Bond Sec. Litig., 51 F.3d 518, 522 (5th Cir. 1995); Valley Forge Christian Coll. v. Americans United for Separation of Church and State, Inc., 454 U.S. 464, 474 (1982) (a "plaintiff generally must assert his own legal rights and interests, and cannot rest his claim to relief on the legal rights or interests of third parties.").

The plaintiffs include a 30-paragraph section about the "GSK Group," but the only products mentioned are Kytril and Zofran. *See* Cplt. ¶¶ 259-288. Rule 9(b) does not permit the claims against GSK to include drug products about which there has been no particularized allegation of fraud or deception. *See, e.g., In re Newbridge Networks Secs. Litig.*, 962 F. Supp. 166, 170-80 (D.D.C. 1997) (holding that allegations regarding certain claims must be dismissed because they did not satisfy Rule 9(b); the case could proceed only with respect to those allegations of fraud that were pleaded with sufficient particularity); *Hunt v. Schotz, Simon, Miller & Co.*, No. 87-2520, 1988 WL 188292, at *2-4 (D.N.J. Aug. 17, 1988) (permitting action to proceed only with respect to those fraud allegations that were pleaded with particularity under Rule 9(b)); *Ohman v. Kahn*, 685 F. Supp. 1302, 1307-09 (S.D.N.Y. 1988) (same).

Plaintiffs' failure to make <u>any</u> specific allegation about non-Medicare brand-name prescription drugs is particularly egregious. In a few paragraphs, the plaintiffs allege that hundreds of unnamed "brand name drugs" reimbursed by private payors are now at issue because "the Defendants" "incentivized" pharmacy benefit managers (PBMs) by "marketing the spread" to them in order to get them to place these drugs "on the PBMs' formularies." Cplt. ¶ 171. There is not a single allegation about which non-Medicare GSK drugs were involved, <u>or</u> how, when, or where GSK (or any other defendant) marketed the spread of these non-Medicare drugs, <u>or</u> which PBMs were involved. As stated in the Consolidated Memorandum, the allegations relating to drugs outside of Medicare should be dismissed as to all defendants, including GSK.

There is one passing reference to the GSK Medicare-eligible drug Navelbine, see Cplt. ¶ 24, but it states only that plaintiff THWF made a payment for Navelbine. There is no allegation about how or when GSK ever made any misrepresentation about the AWP for Navelbine, nor is there an allegation that any plaintiff other than THWF made a payment for Navelbine. Under these circumstances, the claims against GSK cannot involve Navelbine.

CONCLUSION

At most, one plaintiff has alleged a dispute with respect to two GSK drugs, Kytril and Zofran. The Court should dismiss the claims of all other plaintiffs against GSK; and the claims asserted by the one plaintiff, THWF, should be limited to those two drugs. The only allegations of AWP "fraud" against GSK involve those two products.

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Respectfully submitted,

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